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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,097	11/08/2005	Samuel L Stupp	NANO 106 US2 (NU 22088)	2444

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,097	STUPP ET AL.	
	Examiner	Art Unit	
	SAMUEL W. LIU	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6 and 12-14* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 4-6 and 12-14 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/08 has been entered.

The amendment filed 4/21/08 which cancels claims 1-3 and 7-11, and amends claims 4-5 has been entered. Claims 4-6 and 12-14 are under examination. The applicants' request filed 2/19/08 for extension of time of one month has been entered.

IDS

The references cited in the IDS filed 4/21/08 have been considered by Examiner.

Withdrawal of rejections

- The rejection of claims 4-6 and 12-14 under 35 USC 112, second paragraph is withdrawn in light of the amendment of claims 4-5.

- The rejections under 35 USC 102 of (i) claims 4-6 by Wong et al. and (ii) claims 4-6 by Slocik et al. are withdrawn in light of the amendment of claim 4. Both references do not teach the limitation "peptide amphiphile comprising a C_6 or greater hydrocarbon component and a lyophilic peptide component..."

Reiterated-Continuing data and priority

This application is a continuation application of 09561226 filed 4/28/2000 (now US Pat. No. 6924264). Applicant's claim for the benefit of a prior-filed application 60425536 filed 11/12/2002 and 60425689 filed 11/12/2002 under 35 U.S.C. 119(e) is acknowledged. Yet, it is of note that 60425536 has no adequate support for the claimed invention of instant claims 4-6 (see below). Thus, this application does not have the benefit of prior filed 60425536 filed 11/12/2002.

The response filed 4/21/08 submits that 60425689 filed 11/12/02 has support for the instant invention, and thus, states that instant application is still entitled for the benefit back to 11/12/02. Examiner agrees this.

New-Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

●*New matter rejection*

Claims 4-6 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement; this is a new matter rejection. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of (i) "minerals nucleate at the nanofiber surface", and (ii) "peptide amphiphile has a net ionic charge", which as amended into claim 4 on 4/21/08, are not supported in the specification as originally filed.

Applicant can either cancel the new matter or point out specification support for the phrase in the specification as originally filed.

At page 4, the response filed 4/21/08 asserts that support for the "*peptide amphiphile has a net ionic charge*" can be found in Table 2. This is found unpersuasive because the peptides listed in Table 2 are very limited species (under pH 7 condition) of genus "peptide amphiphile", and because the scope of the genus is broader than that of the species, and description of the species cannot substitute for description of the genus. Now said limitation change the scope of the invention. Thus, it is new matter.

At page 5, the response submits that the "*minerals nucleate at the nanofiber surface*" as amended into claims 4 and 21 is supported by original claim 9 which recites a "composition comprising: a material nucleated and grown on the surface of nanofibers in a nanofiber gel…", and by instant abstract: "*templated mineralization of the initially dissolved mineral cations and anions in the mixture occurs with preferential orientation of the mineral crystals along the fiber surfaces within the nanofiber gel.*". Thus, the response requests withdrawal of the new matter rejection.

The applicants' arguments are found unpersuasive because claim 9 discloses "material nucleated …", wherein the "material" can be any substances, and is not necessarily equal to "minerals" recited in the amended claim 4, and because the abstract does not teach "*minerals nucleate*" but rather the "*orientation of the mineral crystals along the fiber surface*" which reflects a result of growth of the "mineral crystals" but is not properly related to the mineral nucleation process.

New-Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (*Nano Lett.* (2002, June) 2, 583-587).

Wong et al. teach a process of preparing SiO_2/Au composite on out-surface of nanoparticles (see Scheme 1, page 585) that contain self-assembled peptide amphiphiles ($Lys_{200}Cys_{30}$) by mixing the solution (**A**) that comprises HBr salt of $Lys_{200}Cys_{30}$ (see Figure 1 legend) with SiO_2 solution (**B**). Said HBr salt has structure "BrH_3N-$(CH_2)_5$-" which is C_5 hydrocarbon component. Solution (**A**) also called "Au solution" (see line 4 of Figure 1 legend) further comprises Au salts which are prepared by citrate reduction taught by the incorporated reference 32 (see "*Discussion of art*"), i.e., Au^{3+} has the same signed ionic charge as positively charged Lys ε-amine group in aqueous solution. Here, the SiO_2/Au composite are ionically charged species; solution **A** is equivalent to instant "first solution" and solution **B** to instant "second solution". In solution **B**, the SiO_2 (colloidal particles of SiO_2 are negatively charged, due to O^- or O^{-2}, see "*Discussion of art*"), i.e., solution B contains ions having opposite signed charge

to $Au^{3+}/Lys_{200}Cys_{30}$. Since mineral "Au" ions has inherent property of acting as nucleation sites for formation of gold nanoparticles (see "*Discussion of art*" in the Office action mailed 10/19/07), Wong et al. teaching is applied to claim 4.

Wong et al teach that formation of $Au^{3+}/Lys_{200}Cys_{30}$ nanofibers and $SiO_2/Lys_{200}Cys_{30}$ nanofibers is time-dependent, e.g., the formation of $SiO_2/Au^{3+}/Lys_{200}Cys_{30}$ nanoparticles emerges after reaction of the solution A with solution B (see Figure 1 legend, lines 7-8). Since the reaction time is inherently relative to controlling size and growth of the materials (SiO_2/Au) on the amphiphilic peptides, the above Wong's teaching is applied to claim 5. Wong et al. teach pH-dependent charge state for lysine ε-amino groups and SiO_2 (see left column, 2nd paragraph, lines 16-22, page 584) and teach that the pH of the solution mixture is 4 (right column, lines 1-2), suggesting a requirement of adjusting pH, which anticipates claim 6.

Scheme 1 shows that the ration of negatively charged silica nanoparticles (n-SiO_2) (see page 584, left column, lines 4-5 from the bottom) to "gold" particles "n-Au" is about 2:1, indicating the resultant nanostructure has net negative charge, as applied to claim 14.

Wong et al. do not expressly teach that the "hydrocarbon component" of the peptide amphiphile is "C_6".

Wong et al. however teach the "hydrocarbon component" of "C_5" (see Fig. 1). Because N-terminal "HBr" portion of the amphiphile peptide is a protection moiety, this "C_5" is considered to be instant "C_6", as applied to claim 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare Au-mineralized amphiphile nanoparticles (see above) wherein the amphiphile peptide comprises "C_6" or greater hydrocarbon moiety. This is because choosing the

protection group having the hydrocarbon moiety longer than "C_5", which has been taught by Wong et al., is well within ordinary knowledge and skill of the one skilled in the art, and/or can be readily determined by the skilled artisan via routine experimentation with reasonable expectation of success. Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Samuel W Liu. Ph.D./
Examiner, Art Unit 1656,
June 2, 2008
/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656